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Sweetening the Bitter Pill Rx to OTC Switches Via a Third Class of Drugs

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I.INTRODUCTION AND SUMMARY

The United States faces a health care crisis in the years ahead. Spiraling costs are quickly outpacing the rate of inflation. Many people do not feel the immediate pressure as the true cost of America's health care is borne by employer or government provided insurance. One can rest assured the consumer is the ultimate payer however.

One significant part of health care cost which is frequently borne directly by consumers is medication. Most insurance does not fully cover this part of health. Many people on fixed income and below the poverty line are seeing their savings devoured by the pharmaceutical industry.

The partial solution to this problem is to switch more drugs from prescription to over the counter status. Over the counter drugs do not require an expensive and annoying visit to the doctor and are consistently cheaper. Also gratifying with OTC switches is that OTC drugs do not require the same direct marketing, a.k.a. gifts, to physicians. In other words, the consumer does not have to pay for that winter conference in Barbados sponsored by Eli Lilly.

Obstacles to more OTC switching include a risk-averse FDA and a hypersensitive and territorial health care industry. The manifestation of these obstacles can be seen with the defeated switch attempts of rogain, H2-blockers,

and oral contraceptives.

In order to overcome these obstacles, the FDA should create a third class of drugs to be dispensed only at the discretion of the pharmacist. This would allow for patient counseling and alleviate the safety concerns of the FDA and health care industry.

II. THE BITTER PILL PROBLEM a. The Problem Detailed.

On Monday, September 28, 1992, a hearing was held before the Select Committee on Aging and the Subcommittee on Housing and Consumer Interests to discuss a problem facing the aged and other consumers in this country. With a few horrifying statistics, the problem was clearly set before everyone present. In 1991, our nation spent almost \$700 billion on health care, over \$32 billion for prescription drugs outside of hospitals. In the previous decade, prescription drug prices went up about three times the rate of inflation. What was a \$20 prescription in 1980 cost \$53.76 in 1991 and is projected to cost \$120 in the year 2000 if something is not done.¹

The pharmaceutical industry has often responded to accusations of price gouging by explaining that a great deal of money is needed to develop the wonder drugs of tomorrow and that patents run out quickly in the drug industry. Unfortunately, this simply does not hold up under scrutiny. The hearing mentioned above also presented the statistic that the average pharmaceutical company has a profit of 15.5%, which triples the profit of the average Fortune 500 company. This 15.5% profit is determined after research and development

¹Prescription Drug Costs: A Bitter Pill to Swallow, Hearing Before the U.S. House of Representatives, Select Committee on Aging, Joint with its Subcommittee on Housing and Consumer Interests, 102nd Congress, 2nd Sess., September 28, 1992.

is taken out as an expense ²

Another statistic the pharmaceutical industry is reluctant to reveal is how much money is spent on marketing the drugs which are so costly to develop. According to data released by the Senate Labor and Human Resources Committee, drug company expenditures on marketing account for about 15% of their revenues, ~ than they spend on research and development. This translates to \$5 billion, or more than \$8,000 per M.D. and D.O. per year.³

What is also interesting about the above figure is that while the consumer ultimately bears the cost of the marketing expense, the doctor receives the benefit. Prescription drug marketing is aimed directly to the health care provider. Relating her personal experience with the pharmaceutical industry, Mary-Margaret Chren, Senior Clinical Instructor, Department of Dermatology, University Hospitals Cleveland, relates that some of the marketing techniques include outright gifts. These gifts included: a check for \$156 made out to her as a senior resident; an invitation to stay - all expenses paid -for six nights at Loew's L'Enfant Plaza, a Washington Hotel; and textbooks valued at \$495.⁴

Making the situation even more unjust is the fact that many of the consumers cannot afford to pick up the tab for the high profit margins and thinly veiled bribery of medical officials. The spiraling costs of health care are always eventually borne by consumers. However,, in the case of prescription drugs the *cost* hits very directly ~id deeply into thA pockets of the *consumer*..

²ibid.

³Mary-Margaret Chren, The Need for Guidelines About Pharmaceutical Promotions Involving Gifts to Physicians, Promotion of Pharmaceuticals: Issues, Trends, ODtions, (Pharmaceutical Products Press, 1992) 136.

⁴Id.

For instance, the average prescription drug costs \$24 plus \$45 for the doctor's appointment to obtain the drug. While some type of health insurance will pick up the doctor's tab, the consumer will pay the prescription costs 75% of the time.⁵

This cost is simply impossible for some to afford. Many people on fixed incomes cannot keep up with prices which triple the rate of inflation.

Illustrating how real the problem has become is the situation in rural New Mexico. Primarily a rural state, many citizens of that state cannot reach a doctor even if they could afford the medicines he would provide. Rather than going without food so that they can buy medicine, the people are more and more frequently crossing over into Mexico to purchase drugs. In Mexico, even prescription drugs can be obtained by simply telling the pharmacists what is wrong and asking for medication. A study in 1990 found that over 87% of the patients at a rural health clinic in New Mexico had obtained medication in Mexico. Low cost and easy accessibility were the primary reason for purchasing the drug.⁶

The great concern with this activity is that the Mexican pharmacist has limited training and resources. Serious illness maybe misdiagnosed. Side effects and adverse drug interaction are much more likely. Furthermore, the individual's doctor cannot track the drug record of the patient.

The inaccessibility of prescription drugs is prevalent throughout the U.S. Of course, many patients do not have the option of travelling somewhere to

⁵Prescription Drug Costs: A Bitter Pill to Swallow.

⁶Stephen R. Tabes, and William H. Wiese, Medications Obtained in Mexico by Patients in Southern New Mexico, Southern Medical Journal, vol. 83, no. 3, March 1990, 271.

obtain cheaper drugs. Frequently the options are to simply go without medicine or go without food. Either choice will cost everyone more than if the drugs had been accessible in the first place. b.A Step in the Riciht Direction - OTC Switches

One partial solution could be switching more drugs off prescription status. The hearing on September 28, 1992 before the Select committee Hearing on Aging considered several options to deal with the problem of escalating prescription costs. Ideas such as price caps and other forms of direct government intervention were mentioned. The problem is massive enough to require more than one simple answer. However, this paper will argue the committee failed to consider a very important option which actually calls for the government to pull back somewhat and let market forces help solve the problem. The FDA should consider switching more drugs over to OTC status.

OTC drugs already have proven invaluable in holding down health care costs and allowing consumers to quickly and efficiently treat their health problems. According to William Soller, senior vice president and director of science and technology, Nonprescription Drug Manufacturers Association, Americans self-treat with OTC drugs 60% of the time. That self-treatment, however, only represents 2% of health care costs.⁷

Before one dismisses the potential for OTC drug expansion, consider the effect when patients decide not to try selftreatment. Soller contends that if consumers switched from self-treatment to medical help only 2% more of the time, the annual increase in patients' office visits would be a staggering 300

⁷William Soller, Outlook for OTC Switches, American Pharmacy, Vol. NS31, No. 2, February 1991, 106.

million per year - more than a 60% increase. To understand the cost of that increase consider Chicago during the 1982 product tampering scare. During the three month scare, patients switched from OTC to prescription 27% more frequently resulting in an added \$382 million to the cost of health care.⁸

The potential in savings after OTC switches can be seen in specific examples as well. Hydrocortisone, (.5%), was switched in 1979. From 1979 to 1981, health care costs were reduced by \$600 million as a result of the switch. Professor Peter Temin at the Massachusetts Institute of Technology calculated that 12 switches of cough/cold medication save the American people \$750 million each year.

With this great potential for savings at the government's disposal, the question becomes why does the government not switch more drugs over to OTC? Not every prescription drug is ideal for switching, but there are many qualified candidates. More drugs are not switched because of the limited resources and natural lethargy of the Food and Drug Administration (FDA). Also limiting switches are health officials' hypersensitivity to safety concerns and self-interest prejudice.

III.THE OBSTACLES TO MORE EFFICIENT HEALTH CARE

a.The Problem of the Limited Resources and Letharcw of the FDA.

To understand how the FDA obstructs prescription to OTC switches, a brief history of OTC would be helpful. The history reveals that when the FDA focuses its limited resources on OTC drugs, much more progress and savings

⁸ibid.

are realized. However, when the agency moves on, these opportunities are lost. The Federal Food, Drug, and Cosmetic Act of 1938 does not contain a specific definition of OTC drugs. By implication of the act however, OTC drugs are drugs having characteristics that do not call for prescription dispensing. The 1951 Humphrey-Durham Amendment to the FDCA formalized the distinction. The FDA's regulation clarified the distinction by permitting a drug to be OTC, unless, because of its toxicity or other potential for harmful effect or because the method of collateral measures necessary to its use, it may safely be sold and used only under the supervision of a practitioner.⁹

For the most part, OTC drugs remained minor remedies for minor problems. They were drugs intended to provide relief of symptoms while nature took its own healing course. In 1972, the FDA began an intensive systematic scrutiny of the OTC drug industry. The investigation focused on the safety, efficacy, and labeling of all OTC drugs. The drugs were grouped into therapeutic classes and advisory panels were established to review each class. The investigation was completed a full eleven years later in 1983, and the panels were disbanded shortly thereafter.¹⁰

The lasting contribution of these panels was the establishment of monographs for each category of drugs. Each monograph contains the active ingredients which may be used in each type of OTC drug. Also included in the monograph is the approved labelling and any required warnings. The system thus requires that each new candidate for OTC must conform to the established

⁹21 CFR 330.10(a)(4)(vi).

¹⁰Commerce Clearing House. Food Drug Cosmetic Law ReDorts, paragraph 72,001.

monograph or submit a new drug application requiring extensive clinical testing and review.¹¹

While the far-reaching review by the advisory panels and establishment of the monograph system helped bring the OTC under control, it also stifled innovation and efficiency. The Nonprescription Drug Manufacturers Association became disgruntled by the process. Having numerous candidates for OTC QID's, the NDMA saw its products tied up for years in a bureaucracy of limited resources and unlimited red tape. From 1951 to 1976, the period before the monograph system, the FDA approved switches at a rate less than one per year. From 1977-84, when the panels focused the FDA's attention to the potential of switches, the FDA approved 2.8 per year. However, after the OTC advisory panels disbanded in the mid-80's, the rate slipped again - back to 1.33 per year.¹² The FDA had focused its mind and limited budget elsewhere.

The FDA's lack of focus has been somewhat alleviated by the creation of the Office of OTC Drug Evaluation and the Nonprescription Drugs Advisory Committee in 1991. According to a 1993 article in the Food & Drug Law Journal, the Nonprescription Drug Advisory Committee was created to review data on the safety and effectiveness of OTC drugs, and to advise the Commissioner and the Office of the OTC Drug Evaluation on monograph or new drug applications.

The creation of the OTC Office and its corresponding advisory panel allows the OTC drug industry greater participation in the evaluation

¹¹ibid.

¹²Soller, 107.

process.¹³ This is a step in the right direction. While government officials might let an application languish for years, private firms will push the issue much harder. The FDA will be forced to give higher priority to OTC switches.

Even with private participation there still remains the problem of the FDA's natural lethargy. Ultimately, the FDA still has to make the decision to approve a prescription to OTC switch. This calls for the FDA to take a risk and open itself up to criticism and responsibility should the drug prove unsafe. An FDA official can make a career of turning down OTC switch applications. However, if an approved OTC switch ever turns out to be a mistake, that official's career can be quickly cut short. Thus, if one is going to try to reach the goal of switching more drugs to OTC, the risk of unsafe switches should be minimized.

b. The Hypersensitivity and Self-Interest of Health Officials.

Compounding the problem of government officials unwilling to take a risk is the hypersensitivity of health officials to safety concerns as well. Both health officials and government agencies have the same basic problem when it comes to making a decision as to whether a drug is a good candidate for OTC. They only experience the downside should their decisions prove wrong. Even worse, health officials face a downside even if the drug switched to OTC proved to be a good choice. Health officials will lose all the direct marketing gifts and donations from the drug company which as mentioned above is very substantial. Even more troubling would be the loss of income as patients effectively treat

¹³Eve E. Bachrach, The FDA's New Over-the-Counter Drug Office and Advisory Committee: An Industry Perspective, 48 Food & Drug Law Journal 563.

their illnesses without ever passing through the physicians' waiting rooms.

Thus, one is not surprised that studies find health officials hypersensitive to safety concerns when discussing OTC switches. A good example of this hypersensitivity is a 1989 study of pharmacists' evaluation of four drugs. A questionnaire was constructed for three potential switch candidates (metaproterenol, cimetidine, and nystatin) and one already switched drug (ibuprofen). The survey revealed that pharmacists perceived all four drugs as being very effective for their suggested nonprescription indication, but they were not comfortable with the safety of the drugs when used on a nonprescription.¹⁴

With the benefit of hindsight one can see that safety concerns, at least for ibuprofen, were exaggerated. Having been on the market for over ten years, ibuprofen has proven a very effective pain reliever. Consumers have shown they can use the drug safely. Whether obtaining oral advice from pharmacists or simply reading the label, consumers are capable of understanding their symptoms and carefully taking the right medication as directed.

The question then becomes whether the health officials' fear of many other drugs are just as poorly grounded. Unfortunately, the FDA is in no position to challenge the medical establishment and health officials when they begin to warn of possible dangers. The public is never allowed to prove that it is capable of treating itself in many cases.

IV.SPECIFIC EXAMPLES

¹⁴Suresh Madhavan and Stephen W. Schondelmeyer, Pharmacists' Evaluation of the Nonprescription Availability of Metaproterenol, Cimetidine, Ibuprofen and Nystatin, American Journal Of Hospital Pharmacy, vol. 46, Dec. 1989, 2492.

In order to show the obstacles to OTC switches in action, three candidates will be discussed: rogaïne, histamine(sub2)-blocker therapy, and oral contraceptives.

a. Rogaïne.

Rogaïne was approved for prescription use in 1987 to treat certain forms of male pattern baldness. FDA's approval was based on efficacy data showing that at four months, the active group had an average increase of 72 hairs while subjects in the placebo group had an average increase of 39 hairs. 27% of patients perceived an increase in hair growth, and physicians perceived hair growth in 32% of patients.¹⁵

Upjohn, the maker of rogaïne, desired to expand the market potential for the drug and submitted an application for switching the drug. Rather than simply relying on the data from the original clinical trials needed for prescription approval, Upjohn submitted a favorable one-year post-marketing surveillance study of 11,222 patients perceptions and satisfaction with rogaïne. With only minor and relatively harmless side effects shown to occur from the drug, Upjohn felt confident the drug would be approved.¹⁶

However, the risk averse nature of the FDA pulled through and the drug was not approved for an OTC switch. The Nonprescription Drugs Advisory Committee voted against the switch because it was feared patients could not accurately diagnose whether the product was needed or not. Rogaïne

¹⁵Rogaïne RX-to-OTC Switch Stumbles on Issue of Baldness Misdiagnosis: Advisory Committee Splits Hairs About Meaningful Efficacy; Actual-Use Study Urged, FDC Report, The Pink Sheet, August 1, 1994, 2.

¹⁶ibid.

only treats a certain form of baldness. Since rogain requires long-term use before any results could be seen, the committee feared consumers would be frustrated and a great deal poorer. Importantly, however, the committee felt there were no real safety concerns.¹⁷

Rogaine remains a prescription product today. Because committee members feared people were incapable of diagnosing what type of baldness they had and would be frustrated, balding consumers remain frustrated. They either must take the trouble of arranging a doctor's appointment, paying for the visit directly out of pocket or through health insurance, and then paying the higher cost of the prescription rogain (which includes the marketing cost to the doctor).

The committee would be better off trusting the consumer as they did with ibuprofen. Patients can diagnose themselves surprisingly well. At the very least, the patients will simply be out of money and frustrated. Many people are in that state of frustration today as they cannot afford to take the time to arrange a doctor's appointment. b.Histamine(sub2)-blockers (H2-blockers).

H2-blockers are prime candidates for an OTC switch. This type of drugs is frequently used in the treatment of peptic ulcer disease. Duodenal ulcer healing occurs in 75-80% of patients after four weeks of H2-blocker treatment. The potential market for this type of drug is quite large. A recent survey found that 25% of Americans had at least one episode of dyspepsia during an average two-week period. The directions for use would be similar to antacids - for the

¹⁷ibid. 1.

relief of heartburn, acid indigestion, sour stomach, hyperacidity, or dyspepsia.¹⁸

There are two main concerns when discussing the switch of H2-blockers to OTC. The first concern is that patients will cease using the drug after the symptoms cease causing incomplete treatment of the disorder and complications. The second concern is that H2 blockers have potential drug interaction problems, particularly with cimetidine.¹⁹

Admittedly, these concerns are much more legitimate than the concerns mentioned for rogain above. However, the two concerns are not sufficient reasons to keep the drug prescription. Since many consumers are using antacids to treat the same symptoms, the problem of untreated underlying disorders is arguably greater with the present system. More importantly, the fear of improper use and drug interaction can be alleviated if the drug is sold only at the discretion of the pharmacists - much as penicillin is today. Of course, this would require more innovation and expense from the FDA. Once again, the consumer's needs are thwarted by bureaucracy as H2-blockers remain available in prescription only. c.Oral Contraceptives.

Talk of providing oral contraceptives OTC has been present ever since this option of birth control was introduced. However, with each passing year the arguments for such a switch grow and the drawbacks seem less important. The biggest argument for such a switch is the chronic problem this country faces with unwanted pregnancies. According to a recent article in

¹⁸Edgar r. Gonzalez and Joseph A. Grillo, Over the Counter Histamine(sub 2) - Blocker Therapy, Annals of PharmacotheraDy, vol. 28, March 1994, 393.

¹⁹ibid.

American Health, there are over 3.5 million unintended pregnancies each year and 1.6 million abortions.²⁰ Frequently, these children are born into families that simply cannot afford to raise them. While social programs can sometimes alleviate some of the pressure, today's political climate suggests that decreasing unwanted pregnancies is a goal upon which most people can agree.

The biggest problem often raised with switching oral contraceptives to OTC is safety. The drugs are known to have serious side effects, particularly with long term use. Dosage and type frequently need adjusting for the optimum effect. The most immediate response to this concern is that while safety should remain a concern, the present system puts more women at risk than any system of OTC oral contraceptives. Pregnancy, especially among the poor where health care access is limited, is much more dangerous than oral contraceptives. Too, other forms of birth control such as abortion are obviously more traumatic and dangerous than taking the pill.

At the bottom of the whole matter is whether women can understand the proper use, limits, and side effects of oral contraceptives. Like other drugs which have been switched, consumers need information and time to mature in understanding of the drug. Once oral contraceptives are switched, that process could begin. The process would not be difficult. The two most important factors to determine dosage are age and smoking status. Mistakes in dosage or type can be troubling - but not extremely serious. Pill overdose leads to vomiting but has never proven fatal - a fact which cannot be said for other

²⁰Winifred Conkling, *Contraceptive Compromise: Switching the Pill to OTC*, American Health, vol. 13, March 1994.

OTC medication.²¹

As with the H2-blockers, oral contraceptives might be good candidates for sale at the discretion of the pharmacist. As Nancy Buc, former senior counsel to the FDA, commented at a Kaiser Family Foundation meeting in California, In the end, who's in charge-the woman or the doctor?²²

V.SOLUTIONS

a.Create a third class of druQs.

The basic dilemma presented in sections II - IV above is that prescription drugs are simply too expensive for many consumers. A switch to OTC can often reduce the costs of medication and make them more accessible to those in need of treatment. However, the FDA and the health care industry are often too lethargic and hypersensitive to safety concerns to switch qualified drugs to OTC. Creating a third class of drugs could be the answer consumers desire and the FDA can accept.

The American Pharmaceutical Association has urged the creation of a third class of drugs for some time. As alluded to above in the discussion of H2-blockers and oral contraceptives, the third class would be a compromise between prescription and OTC drugs. It would be a pharmacist-only class of drugs.

The third class of drugs would combine the benefits of OTC therapy and patient counseling.²³ According to the APhA, pharmacists have been

²¹OCs o-t-c?, The Lancet, vol. 342, September 4, 1993, 565.

²²ibid 566.

²³Sara Martin, Is a Third Class of Drugs in Pharmacy's Future?, American Pharmacy, vol. N531, April 1991, 285.

shown to reduce drug misuse, help patients choose the most appropriate medication, and help prevent drug interactions. Surveys continue to show high credibility ratings for pharmacists. Studies also show that pharmacists are the most accessible health care resource.

One concrete example of how effective pharmacists can be comes from a study completed in California in 1992. One thousand seven hundred and thirteen consumers in five stores in southern California were provided consultation during a 6-month period. Whether the counseling was effective or not was measured by whether the customer purchased a different product than was intended when he or she entered the store. 25.4% purchased a different drug than intended when entering the store. 1.3% were referred to a physician. 13.4% did not purchasing any OTC drugs at all.²⁴ The results clearly shows that consumers can benefit from pharmacist counseling. Also noticeable is that this counseling can save money because patients can be advised against purchasing a drug they do not need.

Candidates for an OTC switch have already passed the rigorous clinical trials in order to be approved as prescription drugs. The FDA's primary concern when failing to approve a switch most often centers around the patient's inability to safely use the drug without a physician's supervision. The hypersensitivity and paternalistic instinct would be reduced if the agency knew a pharmacist was overseeing the drug's use. Further detailed insight into how a third class of drugs could be beneficial is provided by the three examples in

²⁴Michael B. Nichol, et al., The Effects of Consultation on Over-the-Counter Medication Purchasing Decisions, Medical Care, vol. 30, November 1992, 989.

section IV (rogaine, H2-blockers, and oral contraceptives).

The committee which rejected Upjohn's switch application for ro-gaine was concerned with patient misdiagnosis. A pharmacist could help the patient decide whether his or her baldness is appropriate for the drug. Thus, the patient has the best of both worlds. The patient can avoid the expense and hassle of a doctor's appointment while also avoid taking ro-gaine in vain for several months.

As mentioned above, the H2-blockers have not been approved pri-marily because of adverse drug interaction concerns. A pharmacist could find out what drugs the patient is taking and decide if adverse drug interactions are a possibility. In fact, because the pharmacist would have the patient's drug record, the pharmacist might be in a better position to do this than a physician.

A third class of drugs would be ideal for oral contraceptives. The pharmacist could counsel the patient on all the possible side effects and explain the possible side effects if the patient cannot understand the label. Even more importantly, the pharmacist would be more accessible than a physician. Thus, if the patient had further questions or needed further monitoring, the pharmacist could provide that assistance.

One last benefit which must be mentioned from the creation of a third class of drugs. A third class of drugs would decrease the amount of direct marketing to physicians currently taking place by the pharmaceutical industry. Of course, the drug industry would focus its eyes on pharmacists instead. However, since the drug would eventually be moved to full OTC status

as safety concerns are alleviated, direct marketing to pharmacists would be short-lived.

b. More detailed labeling.

Coinciding with the creation of a third class of drugs should be more detailed labelling and warnings of possible side effects. While studies show that consumers frequently ignore warning labels and instructions, the presence of a pharmacist can help solve that problem. Even if the pharmacist was unable to explain the entire package insert or label, she could explain the more important details. The patient could then retain the labelling and refer to it if there are further questions. At the very least, the pharmacist could stress the importance of reading the package labelling and keeping it for future reference.

Fortunately, persuading the FDA to require more detailed labelling on drugs would not be difficult. Labelling has been a common tool for the FDA to disseminate needed health information.

A brief article in Clinical Pharmacy provides an example. In November, 1993, the FDA announced that three categories of drugs would require new warnings. Antacids were required to warn of adverse drug reactions. Laxatives containing water-soluble gums were required to warn the consumer to take the product with plenty of water. Last, sleep aids were required to warn consumers not to take the drug if the patient suffered from certain conditions.²⁵ By requiring such labelling the FDA reveals a belief that the consumer is somewhat capable of understanding labelling. With a pharmacist's assistance, the FDA

²⁵Three Categories of Nonprescription Drug Products to Carry New Warnings, Clinical Pharmacy, vol 12, Nov. 1993, 800.

can rest even easier.

VI.CONCLUSION

Switching more drugs over to OTC status via a third class of drugs deserves consideration. While such a move would not cure all of this nation's health care woes by any means, it would be a step in the right direction. People should be empowered to control their own lives. They should not be held hostage by a greedy prescription drug company, nor should they put blind faith in a self-interested health care industry. To paraphrase Nancy Buc, Who's in charge of our own body anyway - the doctor, the FDA, the drug company, or us?

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